

September 11, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1678-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Administrator Verma,

The undersigned organizations, who represent hundreds of thousands of patients and health care providers, appreciate the opportunity to submit comment in response to the “Laboratory Date of Service Policy”(DOS) in the Centers for Medicare & Medicaid Services (CMS) Hospital Outpatient Prospective Payment System (HOPPS) Proposed Rule for Calendar Year 2018 issued on July 13, 2017.

We are encouraged by the considerations made with regard to DOS in the proposed rule. We are pleased to see CMS work to eliminate unnecessary barriers that hinder patient access to biomarker testing, slow the process of precision medicine, and prevent patients from receiving the best care. Therefore, we are writing to support CMS’ efforts to modernize the DOS policies for separately payable molecular pathology and Advanced Diagnostic Laboratory Tests (ADLTs) in the proposed rule.

We encourage CMS to finalize changes, like those identified in the proposed rule, but urge CMS to ensure that the changes that are made include all appropriate advanced diagnostics. For example, CMS should include in the change contemplated multianalyte assays with algorithmic analysis (MAAAs). Since MAAAs have similar clinical utility and clinical usage patterns, and generally are exempt from packaging, we urge CMS to allow laboratories to bill Medicare for MAAAs, as has been proposed for ADLTs and molecular pathology tests.

We also encourage CMS to remove the limitation that would make the exception available only when the physician “orders the test following the date” of a hospital outpatient’s encounter. This criterion would exclude most liquid biopsy-based tests from qualifying for the exception. The utility of liquid biopsies in the timely determination of treatment options has proven to be unquestionable for certain cancer types, especially when tissue biopsies are not advised based on the patient’s health status or where tumor heterogeneity is not captured through a tissue biopsy.¹ With the inclusion of MAAAs and liquid biopsy tests, we want to advocate for CMS’ observation of how quickly innovation and testing technology in cancer is evolving, therefore, we strongly encourage CMS to consider reviewing this rule, at least on an annual basis, to ensure that patients have access to the right test at the right time.

There is strong evidence that targeted therapies, matched to a specific biomarker, are superior to chemotherapy, in improving survival rates and length of time for patients with metastatic cancer.² Furthermore, certain targeted agents may, in fact, be contraindicated in solid tumors with specific biomarkers.³ However, the complexities within the current DOS rule leads to delayed biomarker testing, limiting patient access to life-saving and life-prolonging therapies, and ultimately creates longer than a 14-day delay for most cancer patients. A recently published paper cites the DOS rule in particular as a serious hurdle for appropriate genomic evaluation of non-small cell lung cancer (NSCLC), and these hurdles have consequences: “These challenges can lead to under genotyping, with a recent series reporting as much as 40% and 60% of patients without guideline recommended EGFR and ALK testing, respectively, and 19% receiving cytotoxic chemotherapy before test result review. These factors also lead to under referral to clinical trials of molecularly targeted agents.”⁴ A second recently published study showed that even when appropriate tests are ordered, delays like the ones created by the current DOS rule can affect treatment decisions. The researchers found that of the patients who received appropriate biomarker testing prior to starting treatment,

79% of EGFR-positive patients and 94% of ALK-positive patients received the appropriate targeted therapy. In contrast, of the patients who did not receive their EGFR or ALK positive diagnoses until four or more weeks had elapsed, only 41% of EGFR-positive patients and 65% of ALK-positive patients received an appropriate targeted therapy during their first line treatment.⁵

In addition to the complexities that the current DOS rule brings to the delay in testing and treatment, it also can create great stress and unnecessary burden for patients facing a short life span and terminal diagnosis. In a recently published study on the increase in time to initiating cancer therapy and association with worsened survival, it was reported that “[t]ime to treatment initiation (TTI) has lengthened significantly over recent years, associated with multiple factors. Increase in TTI is associated with substantial increase in mortality ranging from 0.5-3.2% per week of delay in curative settings such as early-stage breast, lung and pancreas cancers.”⁶ Simplifying access to biomarker testing to shorten TTI, even in early-stage cancer patients, could have a significant impact on those mortality rates by increasing access to adjuvant treatments or adjuvant clinical trials with targeted therapies.

We are grateful for the opportunity to comment on the changes to the Laboratory Date of Service Policy in the proposed rule. Once again, we encourage CMS to finalize these proposed changes, but with additional modifications, and specifically urge CMS to include MAAAs and to amend the criterion about when a test is ordered. We likewise urge CMS to continue to evaluate this policy at least annually to ensure that it does not remain a barrier to patient access to the right test at the right time.

Thank you for your attention to this very important matter.

Sincerely,

American Lung Association
Association of Community Cancer Centers
Caring Ambassadors Program, Inc.
Citizens for Radioactive Radon Reduction
Fight Colorectal Cancer
Free ME from Lung Cancer
Friends of Cancer Research
International Association for the Study of Lung Cancer (IASLC)
LiveLung (Dusty Joy Foundation)
Lung Cancer Alliance
Lung Cancer Research Council .ORG
LUNgevity Foundation
Upstage Lung Cancer

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